

DOUGLAS & LONDON, P.C.
Attorneys At Law
59 Maiden Lane, 6th Floor
New York, NY 10038
(212) 566-7500
FAX: (212) 566-7501
www.DOUGLASANDLONDON.com

Gary J. Douglas
Michael A. London*
Stephanie O'Connor*
Randolph D. Janis

Virginia E. Anello^
Rebecca G. Newman*
Kristin D. Padden^
Robin J. Bond*
Lara J. Say*ⁿ
Alicia P. Ellsayer^f
Michael D. Sharp^f

*Also admitted in NJ

^Also admitted in LA & MA

^Admitted in NJ only

ⁿAlso admitted in NC

^fOf Counsel

November 2, 2017

VIA ECF

Honorable Judge Claire C. Cecchi
United States District Court
District of New Jersey
Martin Luther King Building & U.S. Courthouse
50 Walnut Street
Newark, NJ 07101

In Re: Proton-Pump Inhibitor Products Liability Litigation
2:17-md-2789 (CCC)(MF) (MDL 2789)

Dear Judge Cecchi:

Pursuant to CMO No. 4, the PSC respectfully submits this position statement in response and opposition to Defendants' request and proposed Order requiring each plaintiff to produce purported "proof of use" and "proof of injury" records prior to Defendants having even answered a complaint.

While there are many faults with Defendants' proposed CMO, as detailed herein, the most striking aspect is that Defendants seek to re-craft the Federal Rules of Civil Procedure and the manner by which a plaintiff may pursue a personal injury product liability lawsuit. While the PSC appreciates the magnitude of such an allegation, as discussed herein, this is precisely Defendants' goal that was unwittingly exposed by them through their actions and inactions as detailed below.

To be clear, the PSC does not oppose the production of relevant medical records and pharmacy records by each plaintiff to Defendants. To the contrary, the PSC, all of whom are experienced in pharmaceutical litigation, have never opposed such a request in any MDL or similar consolidated litigations of which they have been a part, and the PSC agrees that such production should take place here – *at the appropriate time and with the appropriate governing parameters.*

November 2, 2017
Page 2

Defendants' astonishing approach has significant and major flaws. First, their approach, which would have production of the "proof of injury" and proof of use" records take place when a plaintiff files his/her individual complaint, would impose a burden on plaintiffs significantly higher than that required by Federal Rule of Civil Procedure 8(a) and the *Twombly/Iqbal* precedent handed down by the U.S. Supreme Court. Second, their approach, which is novel to MDL mass tort proceedings and other consolidated litigations to which the PSC is aware, would run counter to the Federal Rules of Civil Procedure, the Manual on Complex Litigation, normal MDL procedure and discovery as it is generally conducted.¹ Third, the proposal would permit Defendants to challenge – through motion practice – the sufficiency of plaintiffs' medical records, standing alone, to support their causes of action even though the law allows a plaintiff to utilize various forms of evidence, including deposition testimony, to meet his/her burden. Lastly, and related to the third point, Defendants' approach asks this Court to stay all further plaintiff discovery pending such a determination, even though stays of discovery are disfavored because delays in discovery can "create case management problems which impede the court's responsibility to expedite discovery and [can] cause unnecessary litigation expenses and problems." *Thompson v. Warren*, 2015 U.S. Dist. LEXIS 67648, *5 (D.N.J. 2015).

The PSC's approach, by contrast, is by far the superior approach and is one that is utilized in almost every mass tort products liability litigation alleging personal injuries. This approach would have each plaintiff's relevant medical records that are in their possession (as well as those obtained by their counsel), along with HIPAA compliant authorizations for Defendants to obtain same, be produced along with a Plaintiff Fact Sheet ("PFS") to Defendants. This completed PFS, and the accompanying records would be served 45 to 60 days after Defendants serve their Answer(s) – a time-period that would permit each plaintiff adequate time to provide such discovery and information.² (Attached hereto as Exhibit A, is a copy of the PSC's PFS proposal).³ Notably,

¹ We appreciate that Defendants will likely have an example or two to point to where "proof of injury" and "proof of use records" were required, but such examples are not in the context proposed by Defendants (i.e. as a condition precedent to maintaining a lawsuit). For example, in *In Re Prempro Replacement Therapy Products Liability Litigation* (MDL-1507), there was never a requirement to produce proof of injury and/or product identification documents at the time of filing a complaint. Rather, in that MDL, there were subsequent Orders issued specifically to address plaintiffs who did not make specific allegation of what drug(s) they used in their complaint, as well as those who failed to identify the specific drug(s) used in the subsequent PFS later in the litigation. Similarly, in the other example provided by Defendants, *Zofran Products Liability Litigation* (MDL-2657), there was a separate Product Identification Fact Sheet that required plaintiffs to identify the product within 30 days of filing or transfer to the MDL. Plaintiffs then had 30 days after service of the Product Identification Fact Sheet to produce pharmacy, insurance, medical, or other records that identify the manufacturer of the product in question. However, the *Zofran* litigation did not require the product identification and/or production of such documents at the time of filing the complaint as the Defendant seek to do here. Further, the PSC submits that the *Zofran* litigation was an anomaly and not in accord with mass tort precedent. Indeed, the fact that there appears to be only one case on point significantly reinforces that this is not the normal procedure.

² The parties are contemplating a process whereby Defendants can utilize a Short Form Answer or a Notice of Answer that provides a general denial and assertion of Affirmative Defenses only.

³ Of note, while the PFS proposal did not provide a date by which the PFS would be due (or what would be due with it), during the negotiations surrounding these matters, the PSC made clear to Defendants that its proposal was that the PFS would become due either 45 to 60 days following Defendants Answers(s), and that with the PFS, the Plaintiffs would provide their relevant medical records and duly executed authorizations to obtain same, as well as any and all relevant medical records obtained by Plaintiff's counsel. (See e.g. Exhibit B, annexed hereto, transmittal email on behalf of PSC from Michael London, Esq. dated September 7, 2017, enclosing PFS and the email proposal.)

November 2, 2017

Page 3

the PSC's proposal does not allow Defendants to challenge the adequacy or sufficiency of a plaintiff's medical records in order for the plaintiff to maintain his/her lawsuit.

Before addressing the flaws in Defendants' proposal in detail, it should be understood that Defendants' proposal is nothing more than an effort to change mass tort litigation practice and perhaps overall policy, rather than simply a litigation of disputed factual and causation based issues. Their new rejection of the PSC's proposal and proceeding with a PFS and medical records together (which they previously agreed to) as well as their now unwavering demand for "proof of injury" and "proof of use records" at the pleading stage supports that this is not about getting information, but about altering the landscape of the litigation of cases like this.

A. Defendants' Proposal Would Heighten the Pleading Requirements of Federal Rule of Civil Procedure 8(a)

In their dogged path to acquiring "proof of use" and "proof of injury" records at the time of filing, Defendants fail to acknowledge that such a requirement contravenes both the Federal Rules of Civil Procedure and U.S. Supreme Court precedent. As the Court is well aware, Rule 8 of the Fed. R. Civ P. governs the pleading requirements in federal courts; specifically Rule 8 only requires that a complaint, include "(1) a short and plain statement of the grounds for the court's jurisdiction, unless the court already has jurisdiction and the claim needs no new jurisdictional support; (2) a short and plain statement of the claim showing that the pleader is entitled to relief; and (3) a demand for the relief sought, which may include relief in the alternative or different types of relief." This is a far cry from mandating a plaintiff to include evidentiary documents to maintain their claim in a court of law. Further, following the Supreme Court pleading requirements set forth in the *Twombly/Iqbal* line of jurisprudence, New Jersey District Courts have held that the pleading standard does not impose a probability requirement and only requires that a plaintiff's complaint, "calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element." *Cole v. NIBCO, Inc.*, No. 3:13-cv-07871 (FLW)(TJB), 2015 U.S. Dist. LEXIS 65960, at *10-12 (D.N.J. May 20, 2015); see also, *Covington v. Int'l Ass'n of Approved Basketball Officials*, 710 F.3d 114, 118 (3d Cir. 2013)("[a] claimant does not have to set out in detail the facts upon which he bases his claim").

In their complaints plaintiffs are providing the names of the PPI product(s) they took and the injuries they claim resulted therefrom. This information provides Defendants with the notice required by Rule 8(a) and there is nothing in the law that requires that a plaintiff submit medical records, at the pleadings stage, to support allegations in a complaint should a defendant have a speculative concern that the information provided in the complaint is inaccurate. To this end, plaintiffs' counsel abides by the self-policing policy and the general well-settled law regarding pleading requirements, as well as Rule 11 signature requirements, and have no interest in filing and/or maintaining unfounded lawsuits. Moreover, it is the plaintiff, and not the defendant, who is in peril if he/she fails to name the appropriate party(ies).

B. The Production of Medical Records is Part of the Discovery Process and the PSC's Proposal has Proven to be a Successful Approach to Plaintiff Discovery

As the Court may be aware, PFSs are routinely, and successfully, used in MDLs and consolidated mass tort litigations to secure discovery responses as well as the medical records that

November 2, 2017

Page 4

Defendants seek.⁴ By way of example, in *In Re: Actos (Pioglitazone) Products Liability Litigation* (MDL-2299), each plaintiff was required to produce all medical records in his/her possession, which included pharmacy records, and HIPAA compliant authorizations for defendants to obtain medical records. Similarly, in *In Re: Testosterone Replacement Therapy Products Liability Litigation*, MDL-2545, an MDL which, like this one, involves multiple defendant manufacturers, the parties agreed to a PFS which, when served, would also include medical records in the plaintiff's possession (as well as those obtained by counsel), including pharmacy records, as well as authorizations for defendants to obtain medical records.⁵

As such, the fact that Defendants do not agree with the PSC's approach is rather surprising given: (1) that PFSs are a tried and true method for getting defendants the information they need from each and every plaintiff in a timely, efficient and effective manner; and (2) that the AstraZeneca Defendants had previously agreed to such an approach. Indeed, before this MDL was created, the AstraZeneca Defendants had stipulated that, as to certain cases filed in the District of New Jersey, "pharmacy records and other records demonstrating use of the proton pump inhibitor product(s) alleged in the complaint and medical records demonstrating diagnosis of the injury alleged in the complaint and/or the appropriate authorizations to obtains such information" would be provided with a PFS. (*See* Exhibit C, annexed hereto, pp. 3-4.)

Defendants change in tactics and refusal to agree with the PSC's approach is based upon a novel (and flawed) claim by them that production of medical records is not discovery. Rather, they characterize it as a needed step to determine a "threshold" matter – whether plaintiffs are lying or being inaccurate in their pleadings, or whether counsel did their "due diligence" in preparing the plaintiffs' complaints – in essence accusing plaintiffs' counsel of violating Rule 11. That Defendants actually fail to characterize medical records as discovery is not only insulting, but most importantly it is a red herring. Defendants are clearly seeking production of plaintiffs' medical records (that establish "proof of injury" and "proof of use") at the time of the filing of a complaint and this Court's resolution of any disputes at the onset in an effort to overwhelm the plaintiffs, their counsel and this Court so as to prevent and/or delay their own pleading and discovery obligations from kicking in.

Further, in seeking these "threshold" records, Defendants appear to be abandoning any form of plaintiff discovery, including the PFS, or significantly deferring it until such a preliminary

⁴ The PFS is a discovery device used in lieu of interrogatories, and is a document that is typically agreed to by the parties in advance so as to remove all objections and to allow the defendants to receive discovery responses in a form-like fashion without objections. Further, a PFS typically concludes with a section related to document demands, which would include medical records, and other requests for relevant documents a plaintiff might maintain (e.g. photos, pill bottles, etc.).

⁵ *See also* *See also e.g.*; *In Re Yasmin and Yaz (Drospirenone) Marketing, Sales Practices and Products Liability Litigation* (MDL-2100); *In Re Eliquis (Apixaban) Products Liability Litigation* (MDL-2754); *In Re: Xarelto (Rivaroxaban) Products Liability Litigation* (MDL-2592); *In Re: Bextra and Celebrex Marketing Sales Practices and Products Liability Litigation* (MDL-1699); *In Re: Pradaxa (Dabigatran Extexilate) Products Liability Litigation* (MDL-2385); *In Re: Benicar (Olmesartan) Products Liability Litigation* (MDL-2602); *In Re: Vioxx® Products Liability Litigation* (MDL-1657); *In Re: Kugel Mesh Hernia Patch Products Liability Litigation* (MDL-1842); *In Re: Nuva Ring Products Liability Litigation* (MDL-1964); and *In Re: Lipitor (Atorvastatin Calcium) Marketing, Sales Practices and Products Liability Litigation* (MDL- 2502). Upon request, the PSC can provide additional examples of consolidated product liability litigations in which PFS's were used and medical records and authorizations were served contemporaneously therewith.

November 2, 2017

Page 5

resolution is made by this Court, as evidenced by an e-mail sent on October 30, 2017 from Defense Counsel John Camp to Plaintiffs' Counsel Michael London. (See Exhibit D, annexed hereto.) In this email, Defendants, in response to the PSC's efforts to discuss medical record production in connection with a PFS,⁶ acknowledge that they are only willing to seek pre-discovery discovery stating: "[y]our e-mail below refers to an effort to negotiate a Plaintiff Fact Sheet, while Defendants are talking about a mechanism that is designed to precede discovery and a PFS."

Defendants' position that medical records are not discovery, but only a "threshold" matter, is not only contrary to sheer common sense, it is invalidated by tried and true MDL practice, discussed *supra*, the Manual on Complex Litigation ("Manual"), this Court's directive at the September 12, 2017 conference and case law from the Third Circuit.

To illustrate, the Manual expressly states that, "individual plaintiffs' conduct, causation, and injuries,"⁷ form a distinct dimension of *discovery* in mass tort cases. Additionally, the Manual states that judges should begin determining and defining the scope of *discovery* at the initial case management conference,⁸ which is exactly what Your Honor's September 12, 2017 directive regarding proof of injury and PFSs did. Specifically, Your Honor when discussing discovery stated, and Plaintiffs agree, that:

I mean, certainly at this point there is agreement that certain proof of injury materials have to be produced and I don't think anyone is quarreling with that or has any issue with it. So I guess the finer points in terms of the plaintiff and defendant fact sheets, you can confer on that.⁹

The Court's directive makes sense because, as previously mentioned, the records sought by Defendants clearly fall under the purview of discovery, and Plaintiff Fact Sheets are routinely,

⁶ As the Court is aware, the use of a PFS had been discussed among the New Jersey Plaintiffs and the AstraZeneca Defendants for months prior to formation of the MDL. Indeed, AstraZeneca and certain of the New Jersey Plaintiffs stipulated to the use of a PFS in May of 2017 which the parties agreed would include the production of medical records and pharmacy records as well as authorizations to obtain same. (See Exhibit C, annexed hereto, pp. 3-4). Even after formation of the MDL and consistent with Your Honor's guidance, the PSC has made numerous attempts to negotiate a PFS with Defendants, all of which have been rejected. The PSC sent Defendants a proposed short form PFS on September 7, 2017 and requested a meet and confer. We received no response until September 18th, at which point, Defendants simply indicated a substantive response would be forthcoming. On September 26th, the PSC again requested a meet-and-confer on the PFS. On September 28th, Defendants responded, merely to propose a call on October 4, 2017. Two days before that call, Defendants sent us a completely different order on the purported "threshold issues of proof of use and proof of injury" that is the subject of this letter. (See Exhibit E, annexed hereto.) After repeated requests by the PSC for a response to their proposed PFS, Defendants sent back a completely different proposal – namely one that abandoned the PFS process in lieu of seeking production of medical records first. To date, Defendants have been unwilling to engage in any meaningful discussion about either PFS proposal, insisting instead that the focus be on their proposed proof of use and proof of injury order.

⁷ Manual for Complex Litigation, Fourth, §22.8 (Also stating, in the context of mass tort cases, judges typically direct initial discovery matters toward Defendants' liability).

⁸ Manual for Complex Litigation, Fourth, §11.31.

⁹ *In Re: Proton-Pump Inhibitor Products Liability Litigation No. II*, September 12, 2017 Court Transcript p. 15.

November 2, 2017
Page 6

and successfully, used to secure these documents, or authorizations thereto, *supra* at pp 3-4.¹⁰ Here, all plaintiffs are willing to produce the medical records they have, as well as duly executed authorizations, as part of the discovery process with their completed PFS.

As to the case law, Courts within the Third Circuit have long recognized the production of medical records as part of the discovery process. *See, e.g., Delanoy v. Twp. of Ocean*, Civil Action No. 13-1555 (PGS)(DEA), 2015 U.S. Dist. LEXIS 83685, at *22 (D.N.J. 2015) (resolving discovery dispute regarding medical records pursuant to Rule 26, ordering that plaintiff produce medical records, declining to enter a protective order as to said records, and noting that discovery sanctions would be imposed if plaintiff continued to not provide the records); *EEOC v. Princeton Healthcare Sys.*, 2012 U.S. Dist. LEXIS 65115, **56-58 (D.N.J. 2012)(allowing discovery of medical records with respect to an ADA claim noting that medical records are a form of discovery that, given their confidential nature, impose a higher burden for discovery than general discovery); *Gonzalez v. Choudhary*, No. 08-0076-JHR-AMD, 2009 U.S. Dist. LEXIS 32342, at *9 (D.N.J. 2009) (finding that a plaintiff's discovery request seeking medical records of other patients presenting at the emergency department of hospital with similar injuries and symptoms was relevant and thus discoverable under Rule 26); *United States v. Westinghouse Elec. Corp.*, 638 F.2d 570, 577 (3d Cir. 1980), *questioned on other grounds*, *Weisberg v. Riverside Twp. Bd. of Educ.*, 180 Fed. Appx. 357, 365 (3d Cir. 2006)(noting that medical records are discoverable though they stand of a different plane than other relevant discoverable material in terms of confidentiality); *Mulholland v. Dietz Co.*, 896 F. Supp. 179, 180 (E.D. Pa 1994)(medical records are not subject to the discovery privilege of confidentiality when a patient brings a personal injury action which calls into question his physical or mental condition); and *Fiorentino v. Cabot Oil & Gas Corp.*, 2011 U.S. Dist. LEXIS 126314, *26-27 (M.D. Pa 2011)(ordering medical records as discoverable under Rule 26(b) even where plaintiff was only proceeding on a medical monitoring claim).

The PSC's proposal, that rightfully treats medical records as discovery, has consistently been adopted because it is a superior discovery tool. It is fundamentally sound and consistent with the Federal Rules of Civil Procedure, the Manual regarding discovery, and virtually every other mass tort litigation before this. Moreover, the Manual even promotes using a PFS as a discovery tool in mass tort litigations and even goes so far as to supply litigants with sample PFS provisions, including language that requires a plaintiff **to provide medical records and/or authorizations at the time the PFS is served.**¹¹ Therefore, it is no surprise that Courts have

¹⁰ The PSC anticipates that Defendants will cite to Your Honor's instructions more than a year ago, prior to the formation of the MDL, at a time when there was only a handful of plaintiffs and the AstraZeneca Defendants before this Court. At that time, Your Honor asked the parties to exchange whatever records they had in their possession. Consistent with those instructions, those plaintiffs provided AstraZeneca with whatever records they had collected at that point and AstraZeneca began production of regulatory files. That exchange, however, occurred long after the filing of Defendants' Answer and was very different than what is proposed now by Defendants. Indeed, that exchange did not require a determination be made by AstraZeneca and the Court that proof of use and/or proof of injury was met before further discovery could be conducted. In fact, at that time when the parties exchanged the information described above, it was acknowledged that moving forward, as the number of cases grew, the parties would need to utilize a Plaintiff Fact Sheet and Defense Fact Sheet for case-specific discovery. Plaintiffs have never wavered from this position. Furthermore, Plaintiffs remain committed to providing their medical records and HIPAA authorizations for same as part of production of the PFS.

¹¹ Manual for Complex Litigation, Fourth, §40.52.

November 2, 2017

Page 7

routinely found that, “completion of the Fact Sheet, and production where applicable,...is less burdensome and more efficient than serving typical interrogatories and/or requests for production of documents on each individual claimant.” *EEOC v. Princeton Healthcare Sys.*, Civil Action No. 10-4126 (PGS), 2012 U.S. Dist. LEXIS 65115, at *72 (D.N.J. May 9, 2012). And as noted above in Footnote 5 above, there are scores of prior MDLs with both these Defendants and these same defense law firms that utilized the format whereby medical records would be produced as part of discovery with a PFS and not as a threshold matter to maintain a lawsuit.

Again, the stark contrast in the two proposals is that Defendants request “proof of injury” and “proof of use records” immediately and want the failure to provide same or failure to provide satisfactory “proof” in the shortest of timeframes to be either a bar to filing a lawsuit or a bar to maintaining a lawsuit.¹² Such an approach has never before been seen in this context in a multidistrict litigation and it is unwarranted and unsupported by any need. Furthermore, such an unprecedented and harsh requirement will likely lead many litigants to elect not to file cases in this MDL, but rather pursue their cases in state court venues across the country.¹³

C. Defendants’ Proposal would Impermissibly have this Court Decide a Summary Judgment Motion at the Pleadings Stage, Before any Discovery has been Conducted

Defendants’ proposal would permit Defendants, after the submission of plaintiffs’ “proof of use” and “proof of injury” medical records, to unilaterally challenge – through motion practice – the sufficiency of these medical records, standing alone, to support their causes of action even though the law allows a plaintiff to utilize various forms of evidence, including deposition testimony, to meet his/her burden. Specifically, Defendants’ proposal suggests that this Court order: “if there is a dispute between the parties as to whether the produced Injury Diagnosis Records are sufficient, the parties may address the dispute through motion practice as outlined below.” *See e.g.* Defendants’ Proposal Case management Order at p. 4. It is this requirement, in addition to the time requirement, that is also troubling to the PSC.

Defendants’ claim that they “only want a one page record” to meet this burden but their language in their proposed CMO is a far cry from that – it clearly requests, by way of a challenge,

¹² Defendants current proposed CMO on this issue has re-named the requests for information to “Injury Diagnosis Records” and “Product Identification Records.” Notwithstanding the parties all appreciate that Defendants request proof of the injury and proof of the product use, if not, they would not still maintain provisions that allow them to challenge the sufficiency and adequacy of the records produced with motion practice.

¹³ The PSC anticipates that Defendants will advocate that having “proof of injury” and “proof of use” records will keep the docket organized and clean, this is simply not accurate. While there may come a time in the course of the litigation for the parties to address the docket and overarching usage/injury issues, the time is not now, but rather as discovery proceeds and advances. Further, the parties may need to be guided by general discovery from Defendants, as well as findings from our experts and then possible *Daubert* and dispositive rulings if Defendants do not agree and accept Plaintiffs’ experts positions on causation, latency and other issues related to use and injuries. While the PSC recognizes that Defendants will seize on the PSC’s seeming refusal to provide “proof of use” and “proof of injury” records as justification to advance the filing of non-meritorious cases in this MDL or in some way causing the Defendants excessive costs, this is not so. The PSC disputes this anticipated, unfounded, allegation. Co-lead counsel and Executive Committee have experience managing most of the largest pharmaceutical MDLs in recent years. And in not one of them has a process like that espoused by Defendants been implemented, yet in each one, we have overseen, the docket was able to be organized and cases categorized for litigation, bellwethers, settlements, and dismissals as necessary.

November 2, 2017
Page 8

a procedure to ensure the records are “sufficient.” Yet, it is known that parties rarely agree as to whether evidence establishes proof – which is why it is evidence and a jury that should determine if a given party has established proving its case. In fact, in many cases, issues of latency (i.e. how soon in proximity was the drug used or when was the process kidney injury diagnosis made) will result in scores of motion practice – yet, these issues should never serve as a bar to maintaining a lawsuit or as a means to challenge the adequacy of discovery as Defendants propose they should be. And often times, doctor testimony and other evidence is often necessary in determining product use and/or injury. All of this underscores why plaintiffs should simply provide contemporaneously with a PFS, the records they have collected and authorizations for Defendants to obtain any others, and that any determination regarding the adequacy of the evidence be made, at the earliest, at the summary judgment stage, rather than as a condition precedent to filing and maintaining a lawsuit at the pleading stage.

D. A Stay of Plaintiffs Discovery is not Supported by the Law

Lastly, Defendants’ approach would have this Court stay all further plaintiff discovery until it or this Court has determined that the records submitted support proof of use or injury. Yet, stays of discovery are disfavored because delays in discovery can “create case management problems which impede the court’s responsibility to expedite discovery and [can] cause unnecessary litigation expenses and problems.” *See Thompson*, 2015 U.S. Dist. LEXIS 67648, *5 (denying motion to stay even where dispositive motion had foundation in the law and could be decided in the movants’ favor). Again, and in contrast, the PSC’s proposal is that a completed PFS be provided in short order (within 45-60 days of the Answer(s)) as well as the medical records maintained by Plaintiff and acquired by counsel.

E. Conclusion

In sum, the PSC cannot agree to and respectfully requests that the Court reject: (1) having a threshold procedure that mandates that “proof of injury” and “proof of use” be a bar for filing and/or maintaining a lawsuit; (2) requiring that, at the pleading stage, medical records provided be deemed “proof of injury” and “proof of use records” and that there be a mechanism to challenge the adequacy of “proof of injury” and “proof of use” records; and (3) treating production of medical records as anything but discovery. Again, medical records are items of discovery to be produced in the ordinary course of litigation – here, contemporaneously with a PFS (as well as duly executed authorizations to obtain same) – and their adequacy should not be challenged before the conclusion of discovery. Defendants’ myopic approach to this issue of “proof of injury” and “proof of use” will be fraught with likely and substantial motion practice challenging the adequacy of “proof of injury” and/or “proof of use records” and will impose an unprecedented burden on Plaintiffs, as well as the Court.

Defendants proposal (which can also rightfully be characterized as policy maneuvering) must be rejected and the PSC’s approach (i.e. service of a PFS with requested relevant documents, including medical records in the possession of a plaintiff and his/her counsel, as well as HIPAA-compliant authorizations, within 45 to 60 days of Defendants serving an Answer, *see* Ex. A.) is the far superior method, as well as the well-settled method in scores of mass tort litigations before this one.

November 2, 2017
Page 9

In this regard, Plaintiff's PFS proposal was tendered to Defendants on September 7, 2017. Since then, Defendants have failed to offer any edits to Plaintiffs' proposal, but instead elected to propose their own PFS, which is significantly longer and more robust. (See Exhibit F, hereto). Whichever PFS is adopted or combination thereof, the plaintiffs should be able to respond to it within 45-60 days following Defendants' Answer(s), and provide their discovery responses then.

To this end, the PSC submits that a PFS and accompanying CMO requiring the production of Plaintiff's relevant records as well as the records maintained/acquired by counsel, and of course duly executed authorizations for the release of all of Plaintiff's relevant medical records, can be negotiated by the parties well within 30 days.

As always, we thank the Court for its time and courtesies.

Respectfully Submitted,

/s/ Christopher A. Seeger

Christopher A. Seeger
SEEGER WEISS LLP
77 Water Street, 26th Fl.
New York, NY 10005
212-584-0700
212-584-0799 (fax)
cseeger@seegerweiss.com

/s/ Stephanie O'Connor

Stephanie O'Connor
Michael A. London
DOUGLAS & LONDON, P.C.
59 Maiden Lane, 6th Fl.
New York, NY 10038
212-566-7500
212-566-5601 (fax)
soconnor@douglasandlondon.com
mlondon@douglasandlondon.com

Plaintiffs' Co-Lead Counsel